REMARKS

Restriction Requirement

In the Restriction Requirement, the Examiner requested Applicants to elect one of the following inventions:

Group I (claims 1 and 2) drawn to polypeptides.

Group II (claim 24) drawn to a method of screening for molecules that bind a polypeptide.

Group III (claims 28, 30, 31, 33, 41, and 42) drawn to antibodies.

Group IV (claims 29, 32, and 34) drawn to methods of disease diagnosis using antibodies.

Group V (claims 35-37) drawn to a method of making a polyclonal antibody and the resultant antibodies.

Group VI (claims 38-40) drawn to a method of making a monoclonal antibody and the resultant antibodies.

Group VII (claim 43) drawn to a method of detecting and purifying a polypeptide.

Group VIII (claim 44) drawn to a method of purifying a polypeptide.

Applicants hereby elect, with traverse, to prosecute Group III, which includes and is drawn to Claims 28, 30, 31, 33, 41, and 42. Applicants reserve the right to prosecute the subject matter of non-elected claims in subsequent divisional applications.

In the Restriction Requirement, the Examiner also required that Applicants elect one polypeptide sequence for examination. Applicants respectfully note that there is only one polypeptide sequence claimed in the application, SEQ ID NO:2, which is encoded by the polynucleotide sequence of SEQ ID NO:1 (see the specification at, for example, p. 3, lines 22-24, and Figures 1A-C). **The claims, as amended herein, recite only SEQ ID NO:2. Thus there is no need for Applicants to make a sequence election.**

Applicants further note that the restriction between the antibodies of Group III (claims 28, 30, 31, 33, 41, and 42) and those of Groups V (claims 35-37) and VI (claims 38-40) was based upon the assumption that the two sets of antibodies bound to different sequences, SEQ ID NO:1 and SEQ ID NO:2. **Because the claims, as amended, are all drawn to antibodies that bind SEQ ID NO:2,**

Groups III, V, and VI sh uld all be examined together, since all are drawn to the same invention, antib dies that bind SEQ ID NO:2.

Applicants note as well that while the methods of claims 35 and 38 are different, both methods produce antibodies (claims 36-37 and claims 39-40) with the same specificity of binding to SEQ ID NO:2 and related sequences. The antibodies of claims 36-37 and 39-40 are both subsets of the antibodies of claim 28, just as the antibodies of claims 30, 41, and 42 are, and thus no additional searches would be required to examine these antibodies. Therefore Groups III, V, and VI can all be examined together without any additional burden on the Examiner.

Applicants also submit that the invention encompassed by Groups IV, VII, and VIII (claims 29, 32, 34, 43, and 44) are drawn to methods of use of the antibodies of Group III, and should be examined together. These method claims recite a product (i.e., an antibody), which is of the same scope as the claimed antibodies being searched by the Examiner. Therefore, it would not be an undue burden on the Examiner to examine these method claims since the searches for the claimed antibodies and these method claims would substantially overlap.

Applicants also suggest that Group I (claims 1 and 2), drawn to the polypeptide bound by the antibodies of Group III, be examined at the same time, also without undue burden on the Examiner. Applicants traverse the Restriction Requirement between Group I and Group III, drawn to the polypeptide and antibodies to the polypeptide, respectively. A search of the prior art to determine the novelty of the polypeptide would substantially overlap with a search of the claims directed to the antibodies. Therefore, applicants submit that examining the prior art for the polypeptide together with the antibodies would involve substantially the same subject matter and would not impose undue burden on the Examiner.

Applicants note in addition that claims directed to the polypeptides of Group I, although of somewhat different scope, have already been examined and allowed in the parent application. Group II (claim 24) is directed to a method of use of the polypeptides of Group I, and could be examined together, without undue burden on the Examiner.

Applicants also respectfully submit that there is minimal additional burden on the Examiner to examine the claims of Groups I and II in addition to the claims elected in the present application, particularly in view of the searches and examination which were already conducted with respect to the

previously issued claims and the additional burden on Applicants to file, prosecute and maintain yet another application in this family, and respectfully request that the Examiner consider doing so.

Additionally, the method claims of Groups IV, VII, and VIII (claims 29, 32, 34, 43, and 44) are entitled to rejoinder upon allowance of a product claim per the Commissioner's Notice in the Official Gazette of March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)" which sets forth the rules, upon allowance of a product claim, for rejoinder of process claims covering the same scope of products. See also M.P.E.P. 821.04 as follows.

> Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. . . The claims to the nonelected invention will be withdrawn from further consideration under 37 C.F.R. 1.142. . . . However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

Thus, Applicants request reconsideration and withdrawal of the Restriction Requirement and examination of the entirety of Applicants' claims.

Docket No.: PF-0059-5 CON

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 09-0108.

Respectfully submitted,

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Docket No.: PF-0059-5 CON

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claims 1, 2, 29, 32, 34, 35, 38, 43, and 44 have been amended as follows:

1. A purified polypeptide comprising an amino acid sequence selected from the group consisting of:

a) the [an] amino acid sequence of SEQ ID NO:2,

b) a naturally-occurring amino acid sequence having at least 90% sequence identity to the amino acid sequence of SEQ ID NO:2,

c) a biologically active fragment of the polypeptide having the amino acid sequence of SEQ ID NO:2, and

d) an immunogenic fragment of the polypeptide having the amino acid sequence of SEQ ID NO:2.

2. An isolated polypeptide of claim 1, having the [an] amino acid sequence of SEQ ID NO:2.

29. **(Once Amended.)** A diagnostic test for a condition or disease associated with the expression of GIPL [P5CRH] in a biological sample comprising the steps of:

a) combining the biological sample with an antibody of claim 28, under conditions suitable for the antibody to bind the polypeptide and form an antibody:polypeptide complex; and

b) detecting the complex, wherein the presence of the complex correlates with the presence of the polypeptide in the biological sample.

32. **(Once Amended.)** A method of diagnosing a condition or disease associated with the expression of GIPL [P5CRH] in a subject, comprising administering to said subject an effective amount of the composition of claim 31.

34. **(Once Amended.)** A method of diagnosing a condition or disease associated with the expression of GIPL [P5CRH] in a subject, comprising administering to said subject an effective amount of the composition of claim 33.

35. **(Once Amended.)** A method of preparing a polyclonal antibody with the specificity of the antibody of claim 28 comprising:

a) immunizing an animal with a polypeptide having the [an] amino acid sequence of SEQ ID NO:2 [SEQ ID NO:1], or an immunogenic fragment thereof, under conditions to elicit an antibody response;

b) isolating antibodies from said animal; and

c) screening the isolated antibodies with the polypeptide, thereby identifying a polyclonal antibody which binds specifically to a polypeptide having the [an] amino acid sequence of SEQ ID NO:2 [SEQ ID NO:1].

38. **(Once Amended.)** A method of making a monoclonal antibody with the specificity of the antibody of claim 28 comprising:

a) immunizing an animal with a polypeptide having the [an] amino acid sequence of SEQ ID NO:2 [SEQ ID NO:1], or an immunogenic fragment thereof, under conditions to elicit an antibody response;

b) isolating antibody producing cells from the animal;

c) fusing the antibody producing cells with immortalized cells to form monoclonal antibody-producing hybridoma cells;

d) culturing the hybridoma cells; and

e) isolating from the culture monoclonal antibody which binds specifically to a polypeptide having the [an] amino acid sequence of SEQ ID NO:2 [SEQ ID NO:1].

43. **(Once Amended.)** A method for detecting a polypeptide having the [an] amino acid sequence of SEQ ID NO:2 [SEQ ID NO:1] in a sample, comprising the steps of:

a) incubating the antibody of claim 28 with a sample under conditions to allow specific binding of the antibody and the polypeptide; and

b) detecting specific binding, wherein specific binding indicates the presence of a polypeptide having the [an] amino acid sequence of SEQ ID NO:2 [SEQ ID NO:1] in the sample.

44. **(Once Amended.)** A method of purifying a polypeptide having the [an] amino acid sequence of SEQ ID NO:2 [SEQ ID NO:1] from a sample, the method comprising:

a) incubating the antibody of claim 28 with a sample under conditions to allow specific binding of the antibody and the polypeptide; and

b) separating the antibody from the sample and obtaining the purified polypeptide having the [an] amino acid sequence of SEQ ID NO:2 [SEQ ID NO:1].